

REMARKS

Claims 1-26 have been canceled, and Claims 27-43 have been added. Claim 44-57 have been newly added. The Examiner issued a Notice of Non-Compliant Amendment pursuant to 37 C.F.R. § 1.121 because the added Claims 27-43 have been withdrawn from consideration by the Examiner as being directed to a non-elected invention. Applicant has amended Claims 27-43 to be directed to a method of the invention. Accordingly, Applicant respectfully requests reconsideration of the pending claims in view of the following remarks.

Claim Objections

The Examiner objected to Claims 14-26 for various informalities. Applicant has canceled Claims 14-26, therefore these objections are moot.

Claim Rejections – 35 U.S.C. § 112

The Examiner rejected Claims 14-26 under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant has canceled Claims 14-26, therefore this rejection is moot.

Claim Rejections – 35 U.S.C. § 102

The Examiner rejected Claims 14-16 and 20 under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,117,829 ("Miller").

Applicant has canceled Claims 14-16 and 20, therefore this rejection is moot.

However, Applicant would like to point out that Miller does not disclose the subject matter of new independent Claim 27. More specifically, Miller does not disclose a method for achieving a desired dose distribution comprising at least the following elements:

- (a) obtaining at least one image from the patient in substantially a treatment position, the image being adequate for dose calculations; and
- (b) adjusting how the dose is received by the patient.

Rather, Miller discloses an alignment system for aligning a specified tissue volume of a patient with a charged-particle beam of a radiation therapy system. The patient is immobilized in a form-fitted pod, and reference radiographs and CT scan data are acquired. The patient is then allowed to return home. The CT scan data is analyzed and used to prepare a treatment plan for the patient. Once the treatment plan is finalized, the patient returns to the treatment location and repositioned within the pod. After the patient is positioned in the beam delivery system, an X-ray image is acquired that produces another radiograph, which is compared to the

previously acquired radiographs (prior to treatment) to verify that the correct entry angle for the beam and correct patient position have been achieved.

The radiograph image acquired by the x-ray source while the patient is positioned in the beam delivery system are only two-dimensional. It is known in the art that two-dimensional x-ray images do not include dose information. Therefore, the radiograph acquired while the patient is positioned in the beam delivery system is not suitable for dose calculation.

For at least these reasons, Miller does not disclose the subject matter of Claim 27. Accordingly, independent Claim 27 is allowable over Miller. Claims 28-43 depend from Claim 27 and are allowable for at least the reasons Claim 27 is allowable. Claims 28-43 may include additional patentable features not discussed herein.

Miller does not disclose the subject matter of new independent Claim 44. More specifically, Miller does not disclose a method of delivering radiation therapy comprising at least the following elements:

- (a) generating a plurality of radiation treatment plans for the patient based on the first image;
- (b) acquiring a second image of the region of interest while the patient is in substantially a treatment position, the second image being three-dimensional; and
- (c) selecting one of the radiation treatment plans based on a position of the region of interest in the second image and dosimetric information in the second image.

As noted above, the radiograph image acquired by the x-ray source in Miller while the patient is positioned in the beam delivery system are only two-dimensional. It is known in the art that two-dimensional x-ray images do not include dose information. Therefore, the radiograph acquired while the patient is positioned in the beam delivery system is not suitable for dose calculation.

For at least these reasons, Miller does not disclose the subject matter of Claim 44. Accordingly, independent Claim 44 is allowable over Miller. Claims 45-49 depend from Claim 44 and are allowable for at least the reasons Claim 44 is allowable. Claims 45-49 may include additional patentable features not discussed herein.

Miller does not disclose the subject matter of new independent Claim 50. More specifically, Miller does not disclose a method of delivering radiation therapy comprising at least the following elements:

(a) acquiring a second image of the patient substantially in a treatment position, the second image being suitable for three-dimensional contouring;

(b) identifying a patient position with respect to a radiation delivery device based on the second image and the contour.

As noted above, the radiograph image acquired by the x-ray source in Miller while the patient is positioned in the beam delivery system are only two-dimensional. Therefore, the radiograph acquired while the patient is positioned in the beam delivery system is not suitable for three-dimensional contouring.

For at least these reasons, Miller does not disclose the subject matter of Claim 50. Accordingly, independent Claim 50 is allowable over Miller. Claims 51-54 depend from Claim 50 and are allowable for at least the reasons Claim 50 is allowable. Claims 51-54 may include additional patentable features not discussed herein.

Claim Rejections – 35 U.S.C. § 103

The Examiner rejected Claims 17-19 under 35 U.S.C. § 103 as being unpatentable over Miller in view of U.S. Patent No. 5,647,663 (“Holmes”).

Applicant has canceled Claims 17-19, therefore this rejection is moot.

However, Applicant would like to point out that Miller and Holmes do not disclose the subject matter of new independent Claim 27. As noted above, Miller does not disclose the subject matter of Claim 27. Holmes does not cure the deficiencies of Miller. Holmes does not disclose a method for achieving a desired dose distribution comprising at least the following elements:

(a) obtaining at least one image from the patient in substantially a treatment position, the image being adequate for dose calculations; and

(b) adjusting how the dose is received by the patient.

Rather, Holmes discloses a treatment planning method for a general radiation therapy machine that provides a plurality of individually controllable radiation beams directed through a treatment volume. The user defines a limited set of discrete intensity values to which each beam will conform. The user then provides an objective function of the computed dose which mathematically describes the clinical objectives of the treatment which one is trying to achieve. From an initial weight for each beam, a computed dose map is then computed and the objective function value is determined for the computed dose map. This value of the objective function is compared to the previous objective function value. Based on this comparison, the initial weights of the beams are adjusted.

Holmes focuses on generation of the treatment plan and does not disclose obtaining an image from the patient in substantially a treatment position, the image being adequate for dose calculations.

For at least these reasons, Miller and Holmes do not disclose the subject matter of Claim 27. Accordingly, independent Claim 27 is allowable over Miller and Holmes. Claims 28-43 depend from Claim 27 and are allowable for at least the reasons Claim 27 is allowable. Claims 28-43 may include additional patentable features not discussed herein.

Miller and Holmes do not disclose the subject matter of new independent Claim 44. As noted above, Miller does not disclose the subject matter of Claim 44. Holmes does not cure the deficiencies of Miller. Holmes does not disclose a method of delivering radiation therapy comprising at least the following elements:

- (a) generating a plurality of radiation treatment plans for the patient based on the first image;
- (b) acquiring a second image of the region of interest while the patient is in substantially a treatment position, the second image being three-dimensional; and
- (c) selecting one of the radiation treatment plans based at least in part on dosimetric information in the second image.

As noted above, Holmes focuses on generation of the treatment plan and does not disclose obtaining an image from the patient in substantially a treatment position, the image being three-dimensional.

For at least these reasons, Miller and Holmes do not disclose the subject matter of Claim 44. Accordingly, independent Claim 44 is allowable over Miller and Holmes. Claims 45-49 depend from Claim 44 and are allowable for at least the reasons Claim 44 is allowable. Claims 45-49 may include additional patentable features not discussed herein.

Miller and Holmes do not disclose the subject matter of new independent Claim 50. As noted above, Miller does not disclose the subject matter of Claim 50. Holmes does not cure the deficiencies of Miller. Holmes does not disclose a method of delivering radiation therapy comprising at least the following elements:

- (a) acquiring a second image of the patient substantially in a treatment position, the second image being suitable for three-dimensional contouring;
- (b) identifying a patient position with respect to a radiation delivery device based on dosimetric information and the contour.

As noted above, Holmes focuses on generation of the treatment plan and does not disclose acquiring an image from the patient in substantially a treatment position, the image being suitable for three-dimensional contouring.

For at least these reasons, Miller and Holmes do not disclose the subject matter of Claim 50. Accordingly, independent Claim 50 is allowable over Miller and Holmes. Claims 51-54 depend from Claim 50 and are allowable for at least the reasons Claim 50 is allowable. Claims 51-54 may include additional patentable features not discussed herein.

The Examiner rejected Claims 21-26 under 35 U.S.C. § 103 as being unpatentable over Miller in view of U.S. Patent Application Publication No. 2003/0007601 ("Jaffray").

Applicant has canceled Claims 21-26, therefore this rejection is moot.

However, Applicant would like to point out that Miller and Jaffray do not disclose the subject matter of new independent Claim 27. As noted above, Miller does not disclose the subject matter of Claim 27. Jaffray does not cure the deficiencies of Miller. Jaffray does not disclose a method for achieving a desired dose distribution comprising at least the following elements:

- (a) obtaining at least one image from the patient in substantially a treatment position, the image being adequate for dose calculations; and
- (b) adjusting how the dose is received by the patient.

Rather, Jaffray discloses a method of generating KV projection images in a cone beam computerized tomography system that provide adequate visualization of soft-tissue structures so as to reduce errors in radiation treatment resulting from organ motion. The planning begins off-line with a planning image on which contours of the target volume and surrounding structures are defined, and margins for target deformation, delivery precision, and delineation precision are applied. Para. 132. Inverse planning is performed according to a given protocol for radiation therapy of the given treatment site. Para. 132. In addition to the reference plan, a plurality of additional plans (the constrained plan set) are generated as a function of various translations and/or rotations of the target volume. Para. 132. Plans are generated at small increments of each possible translation and/or rotation. Para. 132.

The patient is set up on the treatment table in the treatment position, and cone beam computerized tomography images are acquired. Para. 133. The target volume/lesion and surrounding structures are delineated in the cone beam computerized tomography data, thereby identifying the translations and/or rotations of the target volume/lesion relative to the position and orientation in the planning image. Para. 133. Translation of the target volume/lesion may

be corrected by translation of the computer-controlled treatment table, and rotation of the target volume/lesion may be corrected by selection of an appropriate plan from the constrained plan set. Para. 133. A cone beam computerized tomography image acquired immediately prior to, during, or following the treatment procedure can be obtained in order to provide accurate representation of the location of patient anatomy during treatment delivery, which can be stored for off-line review, evaluation, and modification of subsequent treatment sessions. Para. 133.

Jaffray is concerned about proper registration of the target volume and assumes that if the target volume is properly aligned at time 1 and time 2 that the patient will receive the prescribed radiation dose. The system and method of Jaffray do not make adjustments based on dosimetric information.

For at least these reasons, Miller and Jaffray do not disclose the subject matter of Claim 27. Accordingly, independent Claim 27 is allowable over Miller and Jaffray. Claims 28-43 depend from Claim 27 and are allowable for at least the reasons Claim 27 is allowable. Claims 28-43 may include additional patentable features not discussed herein.

Miller and Jaffray do not disclose the subject matter of new independent Claim 44. As noted above, Miller does not disclose the subject matter of Claim 44. Jaffray does not cure the deficiencies of Miller. Jaffray does not disclose a method of delivering radiation therapy comprising at least the following elements:

- (a) generating a plurality of radiation treatment plans for the patient based on the first image;
- (b) acquiring a second image of the region of interest while the patient is in substantially a treatment position, the second image being three-dimensional; and
- (c) selecting one of the radiation treatment plans based at least in part on dosimetric information in the second image.

As noted above in Jaffray, the target volume/lesion and surrounding structures are delineated in the cone beam computerized tomography data, thereby identifying the translations and/or rotations of the target volume/lesion relative to the position and orientation in the planning image. Para. 133. Translation of the target volume/lesion may be corrected by translation of the computer-controlled treatment table, and rotation of the target volume/lesion may be corrected by selection of an appropriate plan from the constrained plan set. Para. 133. In other words, the treatment plan selected for delivery is based on the contours, which identify how the treatment table can be moved to correct translation of the target volume/lesion between

the planning image and the cone beam CT image. Jaffray does not select the treatment plan based on dosimetric information.

For at least these reasons, Miller and Jaffray do not disclose the subject matter of Claim 44. Accordingly, independent Claim 44 is allowable over Miller and Jaffray. Claims 45-49 depend from Claim 44 and are allowable for at least the reasons Claim 44 is allowable. Claims 45-49 may include additional patentable features not discussed herein.

Miller and Jaffray do not disclose the subject matter of new independent Claim 50. As noted above, Miller does not disclose the subject matter of Claim 50. Jaffray does not cure the deficiencies of Miller. Jaffray does not disclose a method of delivering radiation therapy comprising at least the following elements:

(a) identifying a patient position with respect to a radiation delivery device based on dosimetric information and the contour.

As noted above in Jaffray, the target volume/lesion and surrounding structures are delineated in the cone beam computerized tomography data, thereby identifying the translations and/or rotations of the target volume/lesion relative to the position and orientation in the planning image. Para. 133. Translation of the target volume/lesion may be corrected by translation of the computer-controlled treatment table, and rotation of the target volume/lesion may be corrected by selection of an appropriate plan from the constrained plan set. Para. 133. In other words, the patient position for treatment is based on the contours, which identify how the treatment table can be moved to correct translation of the target volume/lesion between the planning image and the cone beam CT image. Jaffray does not identify a patient position based on dosimetric information.

For at least these reasons, Miller and Jaffray do not disclose the subject matter of Claim 50. Accordingly, independent Claim 50 is allowable over Miller and Jaffray. Claims 51-57 depend from Claim 50 and are allowable for at least the reasons Claim 50 is allowable. Claims 51-57 may include additional patentable features not discussed herein.

CONCLUSION

In view of the foregoing, entry of this Amendment and allowance of the pending claims are respectfully requested. The undersigned is available for telephone consultation during normal business hours.

Respectfully submitted,

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